Review of LBAM Environmental Assessment 2007

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Objectives of Review

- Accuracy of data cited (data verification).
- Interpretation of Risk.
- Identification of Data Gaps.

Treatment Scenario

(Photo courtesy of SARDI, Greg Baker)

- Aerial applications of Lepidopteran Pheromones
  - High volatility, insoluble, metabolized by animals.
  - Air treatment concentration: ($\simeq$ 40 µg/m^3), = 167 female (Codling) moths/m^3 (@ 0.24µg/hr)
  - Expected half life in air? 15 days.

Potential infestation level for (Codling) moth:
126,666-380,000 females/acre. (Biocontrol, Touhey, 1990)

Data Verification

- Biological facts and toxicity data were presented accurately –

  with the exception of a units error in reporting mammalian inhalation toxicity.

  - The correct acute inhalation LC_{50}=5.26 mg/L
    - not 5.26 g/L as stated in the EA.

  - Even with the "Units" error, mammalian inhalation toxicity was still correctly characterized as low.

Data Interpretation

- Environmental Assessment accurately evaluated the potential for adverse effects from treatment action as low.

  - **Toxicity values**: Straight-chain-lepidopteran-pheromone (SCLP) acetates are **low**
  - **Exposure** to active ingredient: ***Limited*** to conservative regulated levels of >20 gai/Acre, and 150 gai/acre/yr, so as not to exceed natural emission levels.

$$\text{Risk} = \frac{\text{Exposure}}{\text{Toxicity}}$$

Toxicity ≠ Risk

USEPA Label Review Manual (Aug. 2007)

Table 1. Mammalian Toxicity Categories

Study	Category I DANGER	Category II WARNING	Category III CAUTION	Category IV NONE REQUIRED
Acute Oral LD_{50}	Up to and including 50 mg/kg	> 50 thru 500 mg/kg	> 500 thru 5,000 mg/kg	> 5000 mg/kg
Acute Dermal LD_{50}	Up to and including 200 mg/kg	> 200 thru 2000 mg/kg	> 2,000 thru 5000 mg/kg	> 5000 mg/kg
Acute Inhalation LD_{50}	Up to and including 0.05 mg/liter	> 0.05 thru 0.5 mg/liter	> 0.5 thru 2 mg/liter	* > 2 mg/liter

* Mammalian acute inhalation toxicity for lepidopteran pheromones >5.26 mg/L

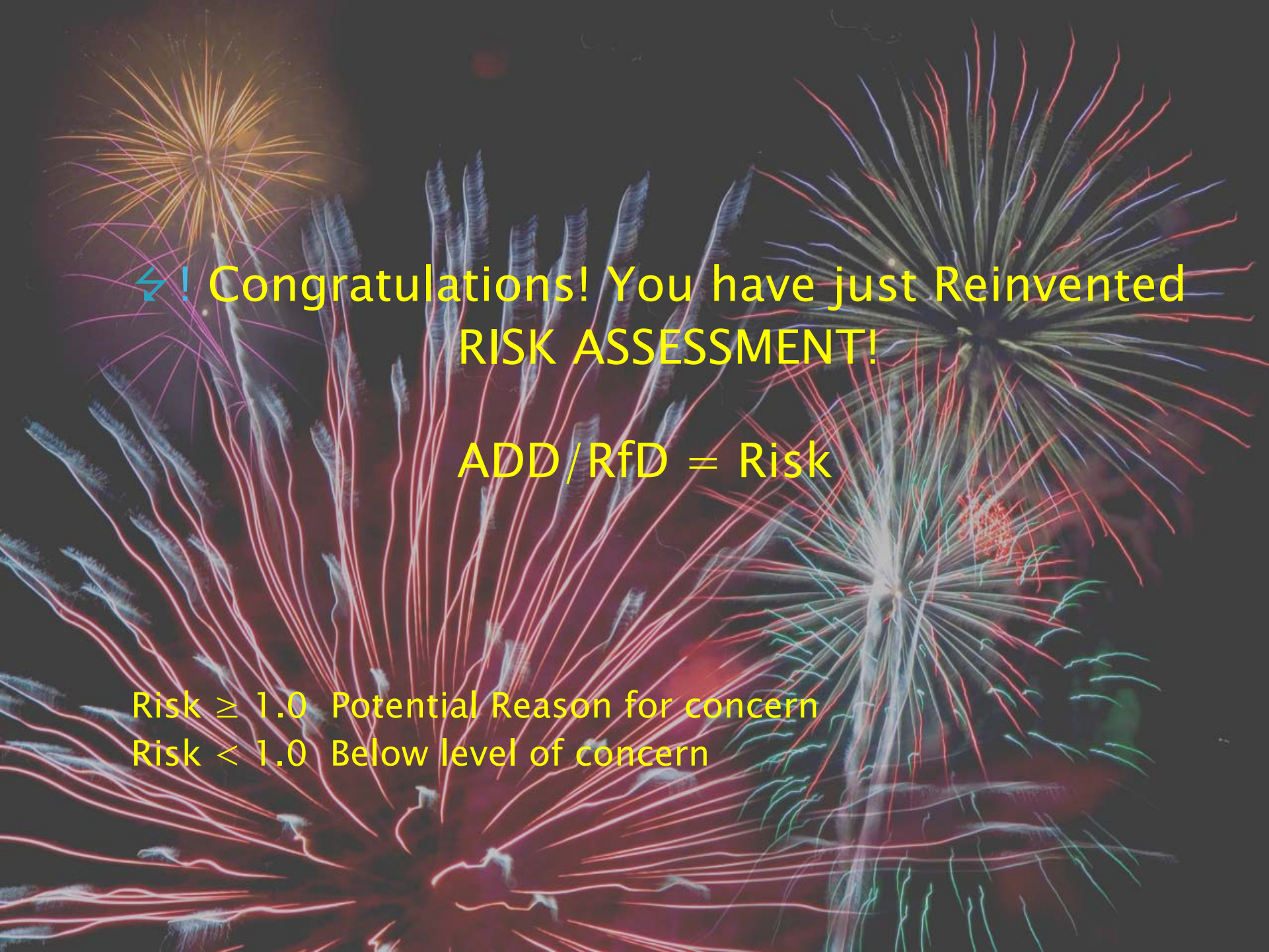
What Do Toxicity Values Mean?

- **Expected Ambient Air Concentrations** of LBAM pheromone. (How much is going to be in the air?)

  = Exposure Dose (ADD)

- Now COMPARE that *exposure,* to a number where you understand the toxic effects-
  - = Toxicity Reference Dose (RfD)
    i.e. No Observable Adverse Effects Level (NOAEL)

ADD/RfD =

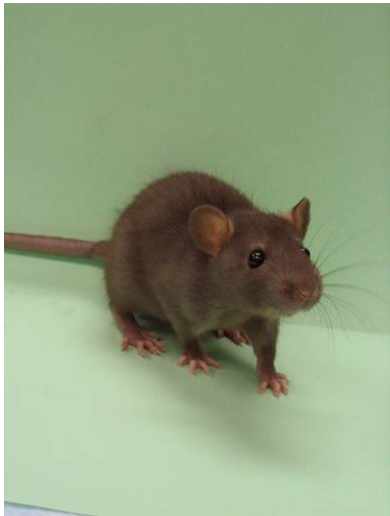

ϟ! Congratulations! You have just Reinvented
RISK ASSESSMENT!
ADD/RfD = Risk
Risk ≥ 1.0 Potential Reason for concern
Risk < 1.0 Below level of concern

Data Gap Analysis: Inhalation

- Lacking: Concentration of pheromone in ambient air, and expected inhalation exposure.
- Lacking: Chronic mammalian inhalation toxicity effects lacking.
- Lacking: Sub-lethal endpoints lacking.

One rat inhalation test noted labored respiration & nasal discharge (Touhey,1990), at the *RfD of 3.3 mg/L (pheromone for Pink Bollworm)

(*RfD was testing limit in this case)



Inhalation: Exposure Concentration Compared to Effects Concentration

RfD: > 3.3 mg/L (Pink bollworm pheromone)
= 3,300,000 µg/m^3

CDFA expected ADD of LBAM pheromone
≃ 40 µg/m^3

Risk = ADD/RfD
= 40 µg/m^3 /3,300,000 µg/m^3
= 1.2 x 10^{-5}
= 0.000012

Include Safety & Uncertainty factors*: 1,000
= 1.2 x 10^{-2}

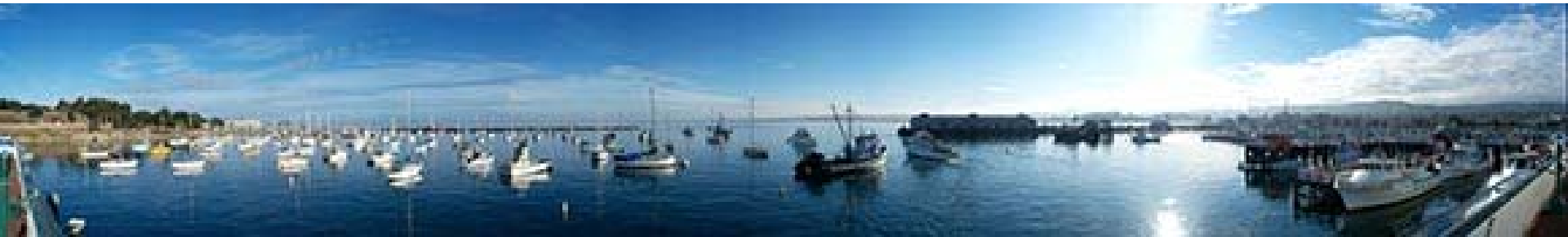
*10 rat to human, 10 sensitive pop (children), 10 for LOEC to NOEC

Data Gaps (continued)…

- Acute freshwater, and marine invertebrate bioassays with *LBAM-specific pheromone* lacking.

  LBAM-specific testing rational:

  - Aquatic invertebrates due to sensitivity of species. LC_{50} values =1.3 to 6.8 (average) mg/L .
  - Amphibians – baseline data: Adult frogs and tadpoles (chronic and developmental effects).
  - *Fish, not warranted.* Sufficient data shows extremely low toxicity (LC_{50} >100 mg/L), "practically non-toxic", – pheromone insoluble.



Conclusions

- Environmental Assessment was accurate & came to appropriate conclusions – *anticipation of no adverse effects from planned treatment action* – **based on available data.**
- Potential **sub-lethal** adverse effects from acute and **chronic** mammalian inhalation exposure are **lacking.**
- **LBAM-specific pheromone tests lacking** for all species, but most important for *freshwater and marine invertebrates*.